UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	1:06-cv-1017-SEB-JMS
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendant.	)	

ORDER GRANTING LIMITED EXTENSION OF STATUTORY STAY

Plaintiff, Eli Lilly and Company ("Lilly"), filed its Motion for Extension of Statutory Stay [Docket No. 225] on September 17, 2008, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), to extend the thirty-month statutory stay of the Food and Drug Administration ("FDA") approval of Defendant's, Teva Pharmaceuticals USA, Inc. ("Teva"), Abbreviated New Drug Application ("ANDA") No. 78-193 for Raloxifene Hydrochloride 60 mg. Tablets.[1] The statutory stay is set to expire on November 16, 2008, and Teva has informed Lilly that it will launch its generic raloxifene hydrochloride upon expiration of the statutory stay, if FDA final approval is obtained by that date. Trial of

[1] On October 14, 2008, Teva filed a sealed request for oral argument on this motion, or, in the alternative, leave to file a surreply [Docket No. 292] in order to address what Teva describes as "at least seven important mischaracterizations of the record in Lilly's Reply in Support of its Motion for Extension of Statutory Stay." Docket No. 292 at 1. Because we are able to reach our decision based upon the briefings submitted and do not rely upon the disputed statements in making our determination, Teva's Request for Oral Argument or Leave to File Surreply is hereby DENIED.

this case is currently set for March 9, 2009.

Lilly requests a six-month extension of the thirty-month statutory stay (which would extend the stay until May 16, 2009) based on what it characterizes as Teva's failure to "reasonably cooperate in expediting the action," pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), as evidenced by Teva's last-minute alteration of its proposed drug product and its "multiple delays in producing critical discovery . . . [which have] adversely affected Lilly's infringement case and trial preparation." Docket No. 225 at 1-2. Lilly contends that, on July 10, 2008, it learned that, more than two years after filing ANDA No. 78-193, Teva altered its proposed drug product by changing: (1) the particle size manufacturing specification of its raloxifene hydrochloride active pharmaceutical ingredient ("API"); and (2) the method of measuring particle size (removing a five-second sonification step). Id. at 2. According to Lilly, these changes directly affect the underlying infringement action and, as a result of Teva's "eleventh hour" change to the proposed generic product and Teva's discovery tactics and delay in producing related documents and the altered raloxifene samples, Lilly has been prejudiced in preparing for trial and developing its infringement case and the stay should be granted.

Teva rejoins that the amendment it made to its raloxifene ANDA, filed with the FDA on July 8, 2008, is nothing more than a minor alteration of the product, and further, that it has reasonably cooperated in advancing this litigation by timely notifying Lilly on July 10, 2008, of the amendment and, within sixty days of filing the amendment, producing approximately 27,000 documents related to Teva's various raloxifene lots and

three industrial batch samples of the altered product that Lilly requested.[2] Thus, Teva

[2] Based on a joint stipulation of the parties, at the status conference held on July 28, 2008, Magistrate Judge Magnus-Stinson ordered Teva to produce, no later than August 18, 2008, the following documents:

a. Samples, certificates of analyses, and particle size analyses of all raloxifene API lots made by procedures described in T00079191-252 and T00089729-32;

b. Analyses of particle size for raloxifene API lots made by procedures described in T00079191-252 and T00089729-32 and Teva's raloxifene API provided to Lilly on December 12, 2006;

c. Correspondence between Teva and Erregierre S.p.A., or other related party, concerning changes in either Erregierre S.p.A.'s or Teva's method for measuring particle size and particle size specification;

d. Correspondence between Teva and Erregierre S.p.A., or other related party, concerning changes in Erregierre S.p.A.'s process for manufacturing Teva's raloxifene with respect to any particle size specification;

e. Documents reflecting the analyses and bases for the change in Teva's or Erregierre S.p.A.'s particle size specification and methodology for measuring particle size reflected in Teva's July 8, 2008, ANDA amendment;

f. Documents concerning the "IPC to control the particle size enlargement" and "a reprocess specific for particle size enlargement" in the scale-up process, referenced in T00089729 and T00089732;

g. List of all bioequivalence studies with reloxifene and an indication of which studies Teva submitted to the FDA in connection with ANDA 78-193;

h. All communications between Teva and FDA concerning ANDA No. 78-193, including any written summaries of telephone communications concerning the same; and

i. All studies comparing the characteristics including solubility and bioequivalence of Teva's raloxifene API lots made by procedures described in T00079191-252 and T00089729-32 and the raloxifene API Teva produced to Lilly on December 12, 2006.

(continued...)

contends that an extension of the thirty-month stay would be inappropriate because Lilly is unable to demonstrate that Teva has failed to reasonably cooperate in advancing this litigation. According to Teva, because ANDA amendments occur "with some frequency without regard for the status of the parallel patent litigation, absent some legislative history to the contrary, the thirty-month statutory stay should be viewed as already having accounted for the possibility of such amendments." Def.'s Resp. at 13. Teva asserts that, rather than focusing on the substantive patent issues that this litigation is intended to address, Lilly is instead dedicating all of its efforts to raising regulatory issues that should be left to the FDA to resolve and which have no bearing on the statutory stay.

As this Court observed in its order granting a limited extension of the statutory stay in Eli Lilly & Co. v. Barr Laboratories, Inc., Cause No. 1:02-cv-1844-SEB-JMS (S.D. Ind. May 27, 2005) (Barker, J.), it appears "important, perhaps essential, that the composition of the generic drug product for which FDA approval is being sought . . . and which Lilly alleges to be the infringing product should be definitively established." Docket No. 174 at 2 (Order Granting Limited Extension of Statutory Stay). That proposition similarly applies here. In light of the fact that Teva has recast its product more than eighteen months after it provided the original sample to Lilly and only eight

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[2](...continued)
Docket No. 206 (Magistrate Judge's Entry for July 28, 2008 Status Conference).

As mentioned above, Magistrate Judge Magnus-Stinson ordered Teva to produce the documents and samples no later than August 18, 2008. Teva produced the materials from August 1, 2008, to September 5, 2008. According to Lilly, more than half of the materials were produced between August 25, 2008, and September 5, 2008.

months before trial is set to commence, we find that, in preparation for trial, Lilly is entitled to have a sufficient opportunity to identify the nature and composition of the raloxifene product as Teva intends for it to be sold.[3]

Teva argues that the circumstances in Barr are distinguishable from the situation at hand because the defendant in Barr had failed to provide Lilly with even one sample of its generic drug product, whereas here, on December 12, 2006, Teva provided Lilly with its original raloxifene sample, and has since produced to Lilly three samples of the altered product (the first on July 28, 2008, the second on August 19, 2008, and the third on September 17, 2008).[4] Therefore, Teva contends that an extension of the statutory stay here is unnecessary because it has fully disclosed all the required information to Lilly in an expeditious fashion. Although Teva correctly cites the factual differences between the case at bar and the situation in Barr, those differences are not viewed by us as determinative on this issue. In Barr, we did not simply extend the statutory stay through the date on which the defendant produced a sample of its product to Lilly. Instead, our order provided that, after the defendant produced the sample, the stay would extend

[3] Although Teva contends that its ANDA amendment is minor and that the original sample it provided to Lilly on December 12, 2006, is still "representative of the product Teva intends to sell upon approval of Teva's ANDA No. 78-193," it concedes that, for purposes of particle-size measurement, its new sample lot "is more representative than [the December 12, 2006] sample of the product that Teva intends to manufacture on a 'commercial scale.'" Exh. 8 at 10-11 (Def.'s Resp. to Interrog. No. 26).

[4] Teva provided three different samples, one from each of the industrial batches referenced in its July 8, 2008, amendment to ANDA No. 78-193. Lilly contends that Teva has not yet produced a sample from a fourth batch of the altered raloxifene product. Pl.'s Mem. at 8.

through "a reasonably expeditious time period for preparing for trial." Id.

A similar extension is warranted here in order to provide Lilly with a reasonable amount of time to allow its expert to test and report on the altered raloxifene samples provided by Teva and for Lilly to assess and utilize that information and analysis in preparation for trial, which is set to commence on March 9, 2009. For the foregoing reasons, the Court hereby EXTENDS until March 9, 2009, in this action the period under 21 U.S.C. § 355(j)(5)(B)(iii) during which the FDA is barred from approving ANDA No. 78-193.[5]

IT IS SO ORDERED.

Date: 10/29/2008

SARAH EVANS BARKER, JUDGE
United States District Court
Southern District of Indiana

[5] In light of the Court's decision to extend the statutory stay, Plaintiff's Motion for Temporary Restraining Order and Preliminary Injunction [Docket No. 262] and Defendant's sealed Motion in Limine to Exclude Certain Statements of Drs. Thisted and Lindstrom in Support of Lilly's Motion for Temporary Restraining Order and Preliminary Injunction [Docket No. 314] are hereby DENIED AS MOOT.

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